CLAIMS:

1. A process for making a pharmaceutical composition suitable for delivery through mucosal membranes comprising:

a) preparing a pharmaceutical agent composition in micellar form in an aqueous medium which has an alkali metal salicylate in a concentration of from 1 to 10 wt./wt.% of the aqueous micellar pharmaceutical agent composition, an alkali metal C8 to C22 alkyl sulphate in a concentration of from 1 to 10 wt./wt.% of the aqueous micellar pharmaceutical agent composition and a pharmaceutically acceptable edetate in a concentration of from 1 to 10 wt./wt.% of the aqueous micellar pharmaceutical agent composition;

b) slowly adding the micellar proteinic pharmaceutical agent composition, while mixing, to at least one absorption enhancing compound, while continuing to mix vigorously, said absorption enhancing compounds being selected from the group consisting of lecithin, hyaluronic acid, pharmaceutically acceptable salts of hyaluronic acid, octylphenoxypolyethoxyethanol, glycolic acid, lactic acid, chamomile extract, cucumber extract, oleic acid, linolenic acid, borage oil, evening of primrose oil, menthol, trihydroxy oxo cholanylglycine and pharmaceutically acceptable salts thereof, glycerin, polyglycerin, lysine, polylysine, polidocanol alkyl ethers and analogues thereof, triolein and mixtures thereof, wherein the amount of each absorption enhancing compound is present in a concentration of from 1 to 10 wt./wt.% of the total formulation, and the total concentration of alkali metal salicylate, alkali metal

C8 to C22 alkyl sulphate, edetate and absorption enhancing compounds is less than 50 wt./wt.% of the formulation.

2. A process according to Claim 1 wherein there is an additional step of adding, while continuing mixing, at least one absorption enhancing compound different to that added in step b), selected from the group consisting of lecithin, hyaluronic acid, pharmaceutically acceptable salts of hyaluronic acid, octylphenoxypolyethoxyethanol, glycolic acid, lactic acid, chamomile extract, cucumber extract, oleic acid, linolenic acid, borage oil, evening of primrose oil, trihydroxy oxo cholanylglycine, glycerin, polyglycerin, lysine, polylysine, triolein and mixtures thereof.

3. A process according to Claim 1 wherein the absorption enhancing compound in step b) is selected from the group consisting of saturated phospholipid, unsaturated phospholipid, phosphatidylcholine, phosphatidyl serine, sphingomyelin, phosphatidylethanolamine, cephalin, lecithin, lysolecithin and mixtures thereof.

4. A process according to Claim 1 wherein one of the absorption enhancing compounds is lecithin and another absorption enhancing compound is selected from the group consisting of hyaluronic acid, pharmaceutically acceptable salts of hyaluronic acid and mixtures thereof, the concentration such absorption enhancing compound being from about 1 to about 5 wt./wt.%.

5. A process according to Claim 1 wherein the micellar absorption enhancing compounds comprise combinations selected from the group consisting of i) saturated

phospholipid and sodium hyaluronate,ii) saturated phospholipid and glycolic acid, iii) lecithin and sodium hyaluronate and iv) saturated phospholipid, glycolic acid and lactic acid.

6. A process according to Claim 1 wherein the proteinic pharmaceutical agent is selected from the group consisting of insulin, heparin, so-called low molecular weight heparin, hirulog, hirugen, huridin, interferons, interleukins, cytokines, mono and polyclonal antibodies, chemotherapeutic agents, vaccines, glycoproteins, bacterial toxoids, hormones, calcitonins, insulin like growth factors (IGF), glucagon like peptides (GLP-1), large molecule antibiotics, protein based thrombolytic compounds, platelet inhibitors, DNA, RNA, gene therapeutics, antisense oligonucleotides, opioids, narcotics, analgesics, NSAIDS, steroids, hypnotics, pain killers and morphine.

7. A process according to Claim 1 wherein in step b) the micellar proteinic pharmaceutical agent composition is added to lecithin, with sonication, to form a mixed micellar composition; and

c) while continuing to mix, adding at least one absorption enhancing compound selected from the group consisting of hyaluronic acid, pharmaceutically acceptable salts of hyaluronic acid, octylphenoxypolyethoxyethanol, glycolic acid, lactic acid, chamomile extract, cucumber extract, oleic acid, linolenic acid, borage oil, evening of primrose oil, trihydroxy oxo cholanylglycine, glycerin, polyglycerin, lysine, polylysine, triolein and mixtures thereof;

wherein the amount of lecithin and the absorption

enhancing compound are each present in a concentration of from 1 to 10 wt./wt.% of the total formulation, and the total concentration of alkali metal salicylate, alkali metal C8 to C22 alkyl sulphate, edetate and absorption enhancing compounds is less than 50 wt./wt.% of the formulation.

8. A process according to Claim 1 wherein the absorption enhancing compound is formed into a film prior to the addition of the micellar pharmaceutical agent composition.

9. A process according Claim 1 wherein subsequent to the addition of the micellar pharmaceutical agent composition a second absorption enhancing compound is added, said second absorption enhancing compound being different from the absorption enhancing compound previously used.

10. A process according to Claim 1 a phenol selected from the group consisting of phenol, methyl phenol and mixtures thereof are added to the micellar formulation and the resulting formulation placed in a container, and the container is subsequently charged with a propellant.

11. A process according to Claim 10 wherein the propellant is selected from the group consisting of tetrafluoroethane, tetrafluoropropane, dimethylfluoropropane, heptafluoropropane, dimethyl ether, n-butane and isobutane.

12. A process according to Claim 1 wherein the pharmaceutical agent is insulin.

13. A process according to Claim 11 wherein the pharmaceutical agent is insulin.

14. A mixed micellar pharmaceutical formulation

comprising a pharmaceutical agent in micellar form, water, an alkali metal C8 to C22 alkyl sulphate in a concentration of from 1 to 10 wt./wt.% of the total formulation, a pharmaceutically acceptable edetate in a concentration of from 1 to 10 wt./wt.% of the total formulation, at least one alkali metal salicylate in a concentration of from 1 to 10 wt./wt.% of the total formulation, and at least one absorption forming compound, said absorption forming compounds being selected from the group consisting of lecithin, hyaluronic acid, pharmaceutically acceptable salts of hyaluronic acid, octylphenoxypolyethoxyethanol, glycolic acid, lactic acid, chamomile extract, cucumber extract, oleic acid, linolenic acid, borage oil, evening of primrose oil, menthol, trihydroxy oxo cholanylglycine and pharmaceutically acceptable salts thereof, glycerin, polyglycerin, lysine, polylysine, polidocanol alkyl ethers and analogues thereof, triolein and mixtures thereof, wherein the amount of each absorption enhancing compound is present in a concentration of from 1 to 10 wt./wt.% of the total formulation, and the total concentration of absorption enhancing compounds are less than 50 wt./wt.% of the formulation.

15. A mixed micellar pharmaceutical formulation according to Claim 14, in which one of the absorption enhancing compounds is lecithin.

16. A formulation according to Claim 14 wherein the alkali metal C8 to C22 alkyl sulphate is sodium lauryl sulphate and the alkali metal salicylate is sodium salicylate.

17. A formulation according to Claim 15 wherein the

lecithin is selected from the group consisting of saturated phospholipid, unsaturated phospholipid, phosphatidylcholine, phosphatidyl serine, sphingomyelin, phosphatidylethanolamine, cephalin, lysolecithin and mixtures thereof.

18. A formulation according to Claim 15 wherein the other absorption enhancing compound is selected from the group consisting of hyaluronic acid, pharmaceutically acceptable salts of hyaluronic acid and mixtures thereof, the concentration such absorption enhancing compound being from about 1 to about 5 wt./wt.%.

19. A formulation according to Claim 14 wherein the formulation comprises combinations selected from the group consisting of i) sodium lauryl sulphate, sodium salicylate, disodium edetate, saturated phospolipid and sodium hyaluronate; ii) sodium lauryl sulphate, sodium salicylate, disodium edetate, lecithin and sodium hyaluronate; iii) sodium lauryl sulphate, sodium salicylate, disodium edetate, sodium hyaluronate and evening of primrose oil; iv) sodium lauryl sulphate, sodium salicylate, disodium edetate, saturated phospolipid and bacitracin; v) sodium lauryl sulphate, sodium salicylate, disodium edetate, saturated phospolipid, sodium hyaluronate and bacitracin; and vi) sodium lauryl sulphate, sodium salicylate, disodium edetate, sodium hyaluronate, oleic acid and gamma linoleic acid.

20. A formulation according to Claim 14 wherein the pharmaceutical agent is selected from the group consisting of insulin, heparin, so-called low molecular

weight heparin, hirulog, hirugen, huridine, interferons, interleukins, cytokins, mono and polyclonal antibodies, chemotherapeutic agents, vaccines, glycoproteins, bacterial toxoids, hormones, calcitonins, insulin like growth factors (IGF), glucagon like peptides (GLP-1), large molecule antibiotics, protein based thrombolytic compounds, platelet inhibitors, DNA, RNA, gene therapeutics antisense oligonucleotides, opioids, narcotics, analgesics, NSAIDS, steroids, hypnotics, pain killers and morphine.

21. A formulation according to Claim 14 wherein the pharmaceutical agent is insulin.

22. A formulation according to Claim 21 in which the absorption enhancing compounds are lecithin and a second absorption enhancing compound selected from the group consisting of hyaluronic acid, pharmaceutically acceptable salts of hyaluronic acid and mixtures thereof.

23. A formulation according to Claim 14 wherein the formulation additionally comprises a phenol selected from the group consisting of phenol, methyl phenol and mixtures thereof.

24. A formulation according to Claim 23 wherein the formulation is contained in an aerosol container and the container is charged with a propellant.

25. A formulation according to Claim 24 wherein the propellant is selected from the group consisting of tetrafluoroethane, tetrafluoropropane, dimethylfluoropropane, heptafluoropropane, dimethyl ether, n-butane and isobutane.

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